

# Maryland's Medicaid Pharmacy Cost-Containment Strategy: Update On The Department's Savings and Work With Stakeholder Group November 2002

## **INTRODUCTION**

During the 2002 Legislative Session, the Department of Health and Mental Hygiene was directed by the Legislature to work with a stakeholder group to identify and attempt to gain consensus on alternative pharmacy cost-containment proposals to some of the State's initial proposals and to report back to the legislature.

This report summarizes the Department's initial cost-containment strategy, provides an update on the work of the Stakeholder Group, and makes recommendations for reaching its fiscal year (FY) 2003 savings target for pharmacy services.

## **DEPARTMENT'S INITIAL PHARMACY COST-CONTAINMENT PROPOSALS**

With pharmacy and nursing home expenditures growing at double-digit rates, the Department focused on these key cost drivers when developing its cost-containment strategy for the FY 2003 budget. The Department's pharmacy cost-containment strategy focused on: changing physicians' prescribing patterns; reducing drug costs; and, increasing patient responsibility. Exhibit 1 provides a summary of the Department's strategy, which would have resulted in an estimated \$12.6 million (general funds) in savings for FY 2003.

### **Exhibit 1: DHMH's Initial Pharmacy Cost-Containment Initiatives**

<b>Initiative</b>	<b>Explanation</b>	<b>FY 03 Savings</b>
<b>Changing Physicians' Prescribing Patterns</b>		
Prior Authorization of Certain Drug Therapies	Making Medicaid more competitive with commercial insurers by increasing prior authorization requirements for all brand-name drugs where a generic equivalent is available; and require prior authorization for brand-name drugs directed at treating arthritis and ulcers to assure that physicians are first attempting to use lower-cost, but effective therapies before trying more expensive therapies.	\$1.5 M (GF)
Patient Profiling	Provide educational tools to physicians where there appears to be an over-utilization of certain medications.	\$100,000 (GF)
<b>Reducing Drug Costs</b>		
Increase Maryland Pharmacy Assistance Program Rebate %	This proposal will permit the Maryland Pharmacy Assistance Program (the State-only pharmacy program) to collect the same level of rebate allowed under the federal manufacturer's rebate program. The increased rebate was implemented in February 2002.	\$2.2 M (GF)
Increase Discount from AWP	Reduce payment for drugs from 10% below average wholesale price (AWP) to 13% below. The State employee plan currently pays pharmacists AWP minus 13% for single-source drugs and deeper discounts for other drugs.	\$5.4 M (GF)
<b>Sharing the Cost of Drugs with Beneficiaries/ Increasing Patient Responsibility</b>		
Increase Co-Pay from \$1.00 to \$2.00 for Medicaid	The \$1.00 co-pay has been in existence since 1992.	\$0.9 M (GF)
Increase Co-Pay from \$5.00 to \$7.50 for MPAP	The \$5.00 co-pay has been in existence since 1992. This will require a State law change.	\$2.5 M (GF)
<b>Savings Total</b>		<b>\$12.6 M (GF)</b>

During the 2002 session, the Department's legislation to increase pharmacy co-pays under the Maryland Pharmacy Assistance Program (MPAP) failed to pass. The Legislature provided \$2.5 million from the Angelos settlement to replace the MPAP co-pay increase. The General Assembly also passed legislation (SB 481) that prohibited any increase in pharmacy co-pays under the Medicaid program, but allowed for a tiered co-pay proposal. The Legislature did not provide additional monies to replace the loss of the increased co-pay proposal for Medicaid. **The Department's new budgeted pharmacy savings target, therefore, was reduced to \$10.1 million (GF).**

Of the Department's remaining initiatives, it was able to quickly implement a higher rebate for MPAP and begin to profile patients. The savings for the higher rebate needed to be recalculated after the approval of the Pharmacy Discount Waiver Program by the Federal Government in July 2002. Under the Waiver, MPAP is a Federal Program that is entitled to federal-matching dollars. The Federal Government, therefore, is now entitled to a percentage of the rebates. The savings were reduced from \$2.2 million (GF) to \$1.65 million (GF), assuming that MPAP will be converted under the Waiver by October 1, 2002.

The Legislature asked the Department to delay implementation of its two more controversial proposals – increasing prior-authorization requirements and reducing pharmacists' reimbursement rate – until the Department had a chance to explore possible alternative proposals with a stakeholder group and report back to the legislature.

## **GROUP OF STAKEHOLDERS**

The Department met with representatives from the key stakeholder groups: physicians, pharmacists, consumers, and drug manufacturers (see attachment 1 for workgroup membership). These were individuals who identified themselves through the legislative process. Since initiatives totaling \$1.75 million were already implemented, **the Department along with the Stakeholder Group were charged with identifying ways to save an additional \$8.35 million (GF).**

The Department has met with the Stakeholder Group on six different occasions. It also met with members of the Stakeholder Group individually and other interested parties like various mental health advocates to understand their specific concerns or cost-containment proposals. Summarized below is the status of the Department's work with the Stakeholder Group.

### **Alternative Proposals With Consensus From Stakeholder Group**

The Department was able to gain consensus on a couple of proposals, **which total \$1.3 million (GF) in savings and include:**

- **Add Vitamin D to the over-the-counter drugs covered by the program (minimal savings less than \$10,000 GF)**
- **Allowing 11 refills (no savings)** Proposal does not provide any savings to the Department, but does make receiving prescriptions more convenient for the

beneficiaries. It also reduces the administrative burden of physicians and pharmacists.

- **Tiered dispensing and copays (savings estimated at \$1.3 million GF for a eight-month period)** Currently, fee-for-service beneficiaries are charged a \$1 copay for all prescriptions. The proposal would discontinue copays for generics and would increase copays for brand-name drugs to \$2. The proposal would be budget neutral, but would produce additional savings from encouraging the use of lower-cost therapies. The same theory applies to a tiered-dispensing fee. A higher dispensing fee would be provided to pharmacists for generics (\$4.69 generics and \$3.69 brand-name drugs; long-term care pharmacists would be reimbursed \$5.65 for generics and \$4.65 for brand-name drugs).

The Department submitted emergency regulations on the above initiatives to the AELR committee on September 13, 2002. The regulations were recently approved and will go into effect November 18, 2002.

Separately, the Department at the suggestion of the Stakeholders plans on implementing measures that do not require regulations to reduce prescription waste by limiting early refills. For example, if a prescription is for 90 days, the Department would require that 90% of the prescription will need to be used before the patient can receive a refill. Savings are estimated to be minimal, approximately \$30,000 - \$40,000 (GF) per year. A suggestion from some of the pharmacists is for the Department to profile pharmacies to determine what percent generics are dispensed versus brand-name drugs. Depending on implementation requirements and costs, the Department would like to begin to profile pharmacies shortly after the tiered dispensing and copays become effective. Profiling pharmacies, hopefully, will encourage pharmacists to work more with physicians to prescribe generics, saving the Department money on the ingredient costs of drugs.

#### *Preferred Drug List, Supplemental Rebate, Prior-Authorization to Prevent Fraud and Abuse*

During the 2002 session, both the Senate and House passed bills (SB 623 and HB 1122) dealing with implementation of a preferred drug list with prior-authorization and supplemental rebates. The legislation, however, was not enacted because of differences in the bills that were not resolved by the end of the session. Nevertheless, given the serious fiscal situation facing the State in the current and upcoming years, Delegate Casper R. Taylor, Jr., the Speaker of the House, and Senator Barbara A. Hoffman, Chairman of Senate Budget and Taxation Committee, and Delegate Howard P. Rawlings, Chairman of House Committee on Appropriations, wrote to the Department requesting it to exercise its regulatory authority to implement a preferred drug list with prior-authorization and supplemental rebates.

A preferred drug list is a **comprehensive list** of clinically effective drugs developed by **clinical experts**, including physicians and pharmacists, who will also take into account patient needs. Drugs not on the list still are provided to beneficiaries through prior-authorizations from their physicians. In this way, the preferred drug list and prior-authorization **still provides access to all drugs** covered under Medicaid. The preferred drug list will encourage the **use of drugs of equal clinical effectiveness but that are less expensive**, such as Ranitidine, a generic drug used to treat ulcers, which costs \$0.10 per tablet. Zantac, the brand-name, clinically-equivalent drug

to Ranitidine, costs \$1.71 per tablet. The P&T Committee would likely have Ranitidine on the preferred-drug list.

The Department reviewed the consumer safeguards and other provisions that were built into both SB 623 and HB 1122 and incorporated many of them in its proposed regulations, including:

- The Department will establish a Pharmaceutical and Therapeutics (P&T) Committee to develop a preferred drug list. The committee will consist of 5 physicians, 5 pharmacists, and 2 consumers. Members will be appointed to three-year terms and will elect a chairman and vice chairman.
- The P&T Committee may make recommendations for a preferred drug list by considering clinical efficacy, cost effectiveness, and the needs of program recipients, such as ease of drug therapy administration and rate of compliance with drug therapy instructions. It also may make recommendations on: prior-authorization criteria; the addition and deletion of drugs from the list; and, conditions or illnesses to be exempted from the preferred drug list and prior-authorization process.
- P&T will meet at least quarterly and review the list at least once every 12 months.
- The Department shall: inform the P&T Committee of any decisions regarding the preferred drug list; annually publish the preferred drug list; maintain an updated preferred drug list that is available electronically; ensure, based upon timely notice from the manufacturer, that any new products are reviewed at the next regularly scheduled meeting of the P&T Committee; provide an expedited review process for new drugs that are considered priority; and provide manufacturers and the public an opportunity to submit written material to the P&T Committee.
- The preferred drug list will cover at least two drugs within each therapeutic class where there are four or more drugs available. Atypical antipsychotic medications and antiretroviral medications will not be subject to the preferred drug list. The P&T Committee will consider off-label usage of FDA-approved drugs when developing the preferred drug list (this is discussed in more detail on page 5).
- The Department may establish prior-authorization requirements for drugs not on the preferred drug list and for specific drugs regardless of whether they are on the preferred drug list to prevent fraud and abuse.
- The Department shall establish a 24-hour hotline to receive requests for prior-authorization. The Department will respond to requests within 24 hours and will respond to requests for reconsideration of adverse decisions within two business days. A 72-hour supply of the prescribed drug will be provided in emergencies, if necessary. Pharmacists will be paid a dispensing fee for emergency supplies.
- The Department will encourage the use of generics and preferred drugs through the use of tiered copays and dispensing fees. Beneficiaries would not be charged a copay for preferred drugs or generics, but they would be charged a \$2 copay for non-preferred drugs and brand-name drugs. A higher dispensing fee would be provided to pharmacists for preferred drugs and generics (\$4.69 for preferred drugs and generics and \$3.69 for non-preferred drugs and brand-name drugs; long-term care pharmacists would be reimbursed \$5.65 for preferred drugs and generics and \$4.65 for non-preferred drugs and brand-name drugs).

Prior to being submitted to the AELR committee, the proposed regulations were given to the Stakeholder Group and other consumer advocate groups for comments. The comments focused largely on having a voluntary preferred drug list versus a mandatory preferred drug list with

prior-authorization. A voluntary preferred drug list was discussed with the Stakeholder Group prior to the Department receiving the Legislators' letters and is preferred by MedChi and the Pharmaceutical Research and Manufacturers of America (PhRMA) to a mandatory list with prior-authorization. However, AARP, one of the key consumer representatives, and the majority of the pharmacists, as well as the Department, believe that the "surest way to experience savings is through a mandatory preferred drug list with prior-authorization." The chain-drug store pharmacists, though, would like the responsibility of getting the prior-authorization to rest solely on the physician, and the long-term care pharmacists believe they should be exempt from the preferred drug list because of the special needs of nursing home residents. The regulations provide a process where physicians can gain approval for a prior-authorization directly or by working with pharmacists. The Department and the P&T Committee will ensure that nursing home residents receive access to necessary medications.

MedChi and PhRMA would like to have all new drugs included on the preferred drug list for a period of six months, or until the P&T Committee and the Department determines that they should be excluded. The Department does not believe that all new drugs should automatically be included on the preferred drug list. Adverse side effects to drugs many times go undetected until the drug has been on the market for several months. Moreover, frequently the newer version of brand-name drugs or "me-too" drugs has just marginal improvements over the previous drugs, but costs substantially more. For instance, Valtrex, which is used to treat viral infections, costs \$3.55 per tablet. The generic drug of the previous version, Acyclovir, only costs \$0.62 per tablet. The P&T Committee through its normal review process is required to review new "me-too" drugs, which is at least quarterly. In addition, in the regulations the Department requires the P&T Committee to provide an expedited review of other priority drugs, ones that offer a significant treatment in a therapeutic class where none existed before.

MedChi expressed concerns that the P&T Committee would automatically exclude drugs from the preferred drug list that have not been specifically tested by the FDA on children. In prior conversations with MedChi, the Department agreed to include the following language in the regulations: "the P&T Committee will not exclude drugs solely on the basis that the drug has not been tested by the FDA for pediatric use." After speaking with our attorneys, however, it became apparent that this language needed to be changed, since the Department is prohibited from paying for drugs that are experimental or investigational (non-FDA-approved drugs) under our current regulations as well as under the Federal Social Security Act. If FDA-approved drugs that were originally targeted for adults are now being prescribed to children, the Department still considers these drugs FDA-approved and will reimburse pharmacists for the cost of the drug as well as for dispensing them. This is referred to as off-label usage. The Department, therefore, addressed MedChi's concerns, while still complying with State and federal regulations, by including in the regulations that the P&T Committee will consider off-label usage of FDA-approved drugs when developing the preferred drug list.

In addition to gathering comments from the Stakeholder Group, the Department met with staff from the Mental Hygiene Administration and with mental health advocates to better understand how the Department can protect quality of care and access to needed mental health drugs. The Department incorporated many of their suggestions either in the proposed regulations or made a commitment to ensure they were addressed during implementation. For instance, in the regulations the Department committed to excluding all atypical antipsychotic medications from the preferred drug list process, making them exempt from prior-authorization. Atypical

antipsychotic medications make up 18% of the Department's drug expenditures. Even though this is significant portion of the Department's drug expenditures, based on the advice of psychiatrists and other experts, the Department felt these drugs warranted being excluded in the regulations. Outside of the regulation process, the Department committed to "grandfathering" in consumers' current mental health regimens, which means that current mental regimens would not be subject to prior-authorization. The Department also agreed to use the existing Mental Health Administration (MHA) P&T Committee as an advisory committee to the P&T Committee. These commitments as well as others, which are outlined in the Department's e-mail dated August 23, 2002 (see attachment 2), will protect enrollees' access to needed drugs and ensure continuity of care. Even after our discussions and agreement to make a number of commitments some representatives from the mental health community still feel that all mental health drugs should be exempt from the preferred drug list. The Department believes access is assured and that it would not be fiscally prudent if it exempted all mental health drugs, which is an additional 18% of the Department's drug expenditures.

The Department is trying to implement cost-containment mechanisms that are already widely accepted by the commercial market. For example, over 95% of commercial payers use a drug formulary, which is even more restrictive than the Department's proposed preferred drug list. Many times commercial plans do not pay for drugs not included on their formularies under any circumstances. Fee-for-service Medicaid and MPAP beneficiaries **will have access to all drugs** not included on the preferred drug list through prior-authorization. If a drug on the preferred drug list had been previously tried and determined unsuccessful for a beneficiary, the provider could authorize the use of a non-preferred drug, and the State would grant the beneficiary access. Requesting prior authorization is not new to physicians. Commercial payers also frequently require physicians to prior-authorize certain prescription drugs as well as other medical services, such as hospital stays. 80% of Medicaid beneficiaries already are subject to formularies and prior authorization under HealthChoice. If implemented effectively, the Department estimates that the savings will be \$6 to \$8 million (general funds) or approximately 5% of total drug expenditures (Maryland's combined fee-for-service and MPAP drug expenditures for FY 2002 totaled \$300.1 million total funds).

Based on discussions with and comments from the Stakeholder Group regarding the preferred drug list, the Department will not be able to address all of the Stakeholder Group's concerns since many of their concerns are contradictory and move the Department further away from guaranteed savings. A mandatory preferred drug list with prior-authorization provides a long-term solution to controlling pharmacy costs without restricting necessary access to needed prescriptions. The Department, therefore, is proceeding with the promulgation of the proposed regulations, which were submitted to the AELR Committee on November 1, 2002 and will allow for full public comment.

Also, the proposed regulation packet includes regulations requiring prior-authorization for any prescription above ten per month for non-institutional adults. Stakeholders raised this proposal during the 2002 legislative session. The proposal will help the Department prevent fraud, abuse, overuse, and dangerous interactions of drugs. Savings are estimated at \$600,000 (GF) for a six-month period. Again, the chain-drug store pharmacists would like the responsibility of getting the prior-authorization to be solely on the provider. Pharmacists, however, must be involved since beneficiaries see multiple providers, who do not necessarily know what the other has prescribed.

### Alternative Proposals Still Under Consideration

Listed below are a number of proposals that were suggested by the Stakeholder Group that the Department still is considering. Two of the proposals -- working with physicians to change prescribing patterns in nursing homes and dosages -- are largely dependent on educating physicians, making savings hard to estimate and guarantee. At this time, the Department wants to continue to explore these proposals but does not want to include them in its savings projection. Specifically, the Department is considering conducting a pilot with four nursing homes to better estimate potential savings. The Department also would like the P&T Committee to discuss developing a program to identify savings by changing dosages.

<b>Initiative</b>	<b>Explanation</b>	<b>FY 03 Savings</b>	<b>Opposition</b>
Prior Authorization of Certain Drug Therapies (Brand-name medically necessary and step-therapy)	Making Medicaid more competitive with commercial insurers by increasing prior authorization requirements for all brand-name drugs where a generic equivalent is available; and require prior authorization for brand-name drugs directed at treating arthritis and ulcers to assure that physicians are first attempting to use lower-cost, but effective therapies before trying more expensive therapies.	<b>Total Year</b> \$1.3M (GF)  <b>6 Months</b> \$0.65 M (GF)	Opposed by MedChi and PhRMA
Limit the number of brand-name drugs per month	No more than four-brand-name drugs per month for non-institutional adults enrolled in Medicaid and MPAP. Mental health drugs, antiviral drugs to treat HIV and insulin and diabetic supplies are exempt. Department is less supportive of this proposal; may be too restrictive	<b>Total Year</b> \$1.6M (GF)  <b>6 Months</b> \$0.8 M (GF)	Opposed by consumer groups. Department thinks it is too restrictive.
Reduce payment for drugs	Reduce payment for drugs from 10% below average wholesale price (AWP) to a higher discount percentage.	TBD	Opposed by pharmacists
Long-term care proposal	Evaluating and making recommendations for changes in the use of drugs by the nursing home population through the use of consultant pharmacists	TBD – The Department has suggested conducting a pilot of four nursing homes to fully understand the potential savings	No opposition – Savings difficult to quantify
Changing the dosages of medications	Create a program where pharmacists would work with physicians to change dosages. Also, the Department could provide education to physicians.	Difficult to quantify savings, since they are largely dependent on provider behavior. Department suggests including it in its contract with First Health	No opposition – Savings difficult to quantify
Requiring prior-authorization for certain medications, such as narcotics or benzodiazepines	Tightening up controls on potential abuse by requiring prior-authorization of certain drugs	TBD	

### Alternative Proposals That The Department Decided Not To Move Forward With

Listed below are five proposals suggested by the Stakeholder Group that the Department has decided to not move forward with due to either minimal savings or legality reasons.

- **Disease Management** Savings from such programs are highly questionable. For example, according to Autumn Dawn Galbreath, M.D., the Director of University of Texas' Disease Management Center, while there is an abundance of literature related to disease management, evidence thus far has not adequately shown that disease management increases efficiency. In addition, an August 2002 study by the Employee Benefits Research Institute revealed a lack of conclusive evidence that disease management provides any long-term health benefits or cost-savings. After reviewing documents provided by PhRMA and doing additional research, the Department found that the only program that has documented Medicaid savings from disease management is the asthma program in Virginia. Most of the beneficiaries who would benefit from an asthma program in Maryland are covered under HealthChoice, and many of the MCOs already have implemented such programs.

The Department did meet with Don Muse, a consultant hired by PhRMA, on the potential savings of disease management programs during the legislative session. The Department has offered to meet with Mr. Muse again. Our initial discussion with Mr. Muse is described below.

Mr. Muse provided the Department with a savings estimate of \$6.1 to \$9.1 million (general funds) from three disease management programs -- asthma, congestive heart failure, and diabetes. The Department reviewed Mr. Muse's methodology and recalculated expected savings using actual data and exempting certain additional populations. When analyzing savings from disease management, in addition to excluding the nursing home population (approximately 16,000 beneficiaries), Mr. Muse should have excluded two other populations as well: fee-for-service enrollees who are on the program for too brief a time to have an affect on health care utilization (approximately 35,000 beneficiaries), and the dually eligible who are not nursing home residents (Medicare and Medicaid; approximately 60,000 beneficiaries). Disease management programs achieve savings through lower costs for services, especially hospital services, in exchange for higher costs for prescription medications. Since Medicare is the primary payer for dual eligibles and pays for physician and hospital care, the largest areas of savings, savings would accrue mostly to the Medicare program. Subsequent to these exclusions, only 18,000 beneficiaries remain.

After accounting for the prevalence of asthma, congestive heart failure, and diabetes, the population that could possibly benefit from disease management is approximately 3,500 to 4,000 beneficiaries. This enrollee group accounts for 8.4% of the total prescription drug expenditures for the fee-for-service population with asthma, congestive heart failure, and diabetes. Based on Mr. Muse's methodology, the Department, therefore, should only be able to realize 8.4% of the \$6.1 to \$9.1 million savings (GF) projected by Mr. Muse, which is approximately \$500,000 to \$765,000 (GF). Again, based on published research



and speaking with other states, the Department feels that even this number is overestimated.

- **Pay incentive bonus to pharmacists for working more closely with physicians to prescribe lower-cost alternatives** Pharmacists will be paid \$1 more for dispensing generics with the new dispensing fees. Also, the new regulations eliminate the copay for generics. This may result in a lower amount of unpaid copays by beneficiaries who cannot afford to pay, if more generics are prescribed. The new copay amounts and dispensing fees, therefore, result in additional financial incentives for pharmacists. The Department does not feel another incentive is necessary.
- **Charge manufacturers a one-time fee for having their drug included under Medicaid** Proposal may violate Federal law.
- **Require prior-authorization for any direct-to-consumer advertised drug** Initial research shows that this may violate FTC laws.
- **Require 34-day supply** Requiring a 34-day supply would reduce the number of unused prescriptions. Currently 98% of all prescriptions are written for a 34-day supply; therefore, potential savings are minimal. The other 2% are for specified maintenance drugs. The Department, however, did change the regulations to require that the initial prescription of a maintenance drug be written for a 34-day supply. All subsequent prescriptions can be written for 100 days.

#### *Alternative Proposals That The Department May Consider In The Future*

There are three alternative proposals that the Department will consider for savings in future fiscal years. These include:

- **Lock-in recipients who abuse prescription coverage** Lock-in recipients who abuse prescription coverage to one pharmacy. Implementation will require extensive MMIS reprogramming, and savings are estimated to be minimal (\$40,000 GF annually). The Department is looking at when it could make these changes given HIPAA and its other priorities.
- **Charge manufacturers a yearly fee for each pharmacy detail person in Maryland** A process would need to be established to register detailers and collect a fee. It also requires a state law change.
- **Physician Profiling** The Department does not plan on profiling physicians' prescribing patterns against other physicians to identify possible outliers in the near-term due to operational issues, but would be willing to consider at a later date. In order to compare physicians across specialties, the Department needs to be able to accurately identify physicians. The Department cannot accomplish this until HIPAA is implemented, which is scheduled for October 2003. Savings are estimated to be minimal (\$50,000 GF annually).

## **RECOMMENDATIONS**

If the AELR Committee approves the Department's proposed regulation packet (preferred drug list and prior-authorization requirements beyond ten prescriptions per month), the Department still will have a savings shortfall in FY 2003 of approximately \$5 to \$6 million, since implementation of the preferred drug list is estimated to take four months after the regulations become effective. In FY 2004, the preferred drug list will be in effect for the entire year, so the Department will be able to achieve at least \$10.1 million savings, if not more.

If the Department is required to meet the \$10.1 million savings target, then the remaining savings for FY 2003 will probably need to be achieved through a number of proposals. Two of the proposals include: increasing the prior-authorization requirements for brand-name drugs and implementing a step-therapy program to switch patients to lower-cost but equally effective therapies. Annual savings are estimated at \$1.3 million or \$650,000 for six months. Currently, when physicians want to prescribe a brand-name drug, if a generic equivalent is available, Maryland requires physicians to indicate on the prescription that the brand-name drug is medically necessary. While this is effective, there are opportunities to improve the prior-authorization process by requesting more information from physicians on the medical need for the brand-name drug. Cox-2 inhibitor painkillers like Vioxx are examples of drugs that would be targeted in the Department's step-therapy program. Vioxx and other Cox-2s are very expensive medications that are used to treat arthritic patients; Vioxx costs \$2.42 a tablet. A high percentage of arthritic patients, however, do not need these expensive drugs and can be treated by simply using ibuprofen, which costs \$0.02 a tablet. A step-therapy program would encourage physicians to first prescribe ibuprofen before prescribing a Cox-2 drug. Additional savings also could be achieved by identifying specific drugs where there seems to be a high rate of potential abuse, such as narcotics and benzodiazepines (tranquilizers/sedatives), and increasing their prior-authorization requirements. Savings estimates would be dependent on the drug selected. Lastly, the Department will probably need to consider reducing pharmacists' reimbursement.

## **Attachment 1: Stakeholder Workgroup**

<b>Name</b>	<b>Organization</b>
<b>Consumers</b>	
Jack Knox and Donna DeLeno	AARP
Kevin Lindamood	Healthcare For The Homeless
Jane O’Leary	Catholic Charities
<b>Pharmacists</b>	
Stanton Aides	NeighborCare
John Balch	PharmaCare
Paul Baldwin	Genesis Health Ventures
Arnold Clayman	NeighborCare
Marvin Freedenberg	NeighborCare
Stuart Gordon	National Association of Chain Drug Stores
Michael Johansen	Representative for Chain-Drug Stores
Jerold Kempler	Omnicare
Mark Levi	EPIC Pharmacies
Howard Schiff	Maryland Pharmacists Association
Robin Shaivitz	Representative for Rite Aid
Dennis Rasmussen	Representative for EPIC Pharmacies
<b>Physicians</b>	
Pam Metz Kasemeyer	MedChi
<b>Drug Manufacturers</b>	
Jan Burrus	PhRMA (GlaxoSmithKline)
Andrew Corsig	PhRMA
Deron Johnson	PhRMA
Donna Stephens	PhRMA (Bayer)

### **Meeting Dates:**

January 25, 2002

February 8, 2002

March 27, 2002

May 17, 2002

August 22, 2002

September 12, 2002

## **Attachment 2 (copy of e-mail that was sent to mental health advocates on August 23, 2003)**

### ***E-mail sent to:***

**Providers:** Dr. Fred Webber

Marie Mackowick, Director of Pharmacy, Crownesville Hospital Center

**Advocates:** Barbara Bellack and Libby Pedrazzani, National Alliance for the Mentally Ill

Walter S. Hill, Washington Psychiatric Society

Herb Cromwell and Lori Doyle, The Community Behavioral Health Association of MD, Inc.

Kenneth R. Wireman, On Our Own of Maryland

Linda J. Raines and Terezia Bohrer, Mental Health Association of Maryland, Inc.

Thank you for meeting with us on August 14 to discuss options for containing mental health pharmacy costs in the current financial climate of the Department of Health and Mental Hygiene. We appreciate your input on the development of a Pharmacy and Therapeutics (P&T) Committee, preferred-drug list, and prior-authorization process and have incorporated many of your suggestions for maintaining and improving health care quality for mental health consumers. The Department is committed to providing access to high-quality, mental health pharmaceutical treatment, and we believe that through the measures included in proposed regulations and through additional activities we can protect quality of care and access to needed mental health drugs. Therefore, we are still planning to proceed with implementing the preferred drug list and prior authorization, and we want to continue working with you on this important issue.

### **PROPOSED REGULATIONS**

The following consumer protections are outlined in the Department's proposed regulations.

#### **Ensure High-Quality Health Care**

The development of the preferred drug list will be based on clinical efficacy. Consideration of the needs of Program recipients, such as the ease of drug therapy administration, rate of compliance with drug therapy instructions, and frequency of prior authorization is required in the regulations. The P&T Committee may also recommend conditions or illnesses to be exempted from prior authorization based on clinical data.

#### **Protection of Access**

Multiple measures will protect consumers' access to drugs. All atypical antipsychotic medications (as well as antiretroviral medications) will be automatically excluded from the preferred drug list process, making them exempt from prior authorization. The preferred drug list will include a choice of at least two drugs for each therapeutic class in which there are four or more drugs. The list will be comprehensive and will include drugs in every therapeutic class, unless excluded from the preferred drug list process in regulations or by the P&T Committee. The P&T Committee will develop an expedited process to review new drugs that are considered life saving for inclusion on the preferred drug list.

The specific needs of mental health consumers that you mentioned, such as medications losing their effectiveness over time and consumers finding that certain medications simply do not work for them, are valid reasons for having access to drugs not on the preferred drug list.

Consumers would be provided access to drugs not on the preferred drug list through prior authorization. As such, the preferred drug list provides more comprehensive access to drugs than formularies used in the private sector. Many times commercial plans do not pay for drugs not included on their formularies under any circumstances.

Guaranteed time frames for prior authorization responses and appeals processes further protect consumers. The Department will respond to prior authorization requests within 24 hours, and will respond to requests for reconsideration of adverse decisions within two business days. When prior authorization is not granted in the 24-hour time frame, a 72-hour emergency supply of the prescribed drug will be dispensed.

### **Mental Health P&T Committee Representation**

As you suggested, the P&T Committee will include representatives from mental health. Of the five pharmacists, one will have expertise with mental health drugs. Of the five physicians, one will be a psychiatrist. We have incorporated your input to increase the number of consumer representatives. We have increased the number of consumers to two. We will seek your help in identifying potential P&T Committee members.

### **ADDITIONAL ACTIVITIES**

In addition to the protections outlined in the regulations, we are fully committed to incorporating your other suggestions as we establish and implement the P&T Committee, preferred drug list, and prior-authorization process.

### **Grandfathering -In Current Mental Health Drug Regimens**

We are implementing your suggestion to permanently “grandfather in” consumers’ current mental health drug regimens. In order to protect successful drug therapies, individuals’ current mental health drug regimens will not be subject to prior authorization. Although this level of detail is not appropriate for regulations, the Department is committed to this.

### **Coordination with Mental Hygiene Administration P&T Committee**

The existing Mental Hygiene Administration (MHA) P&T Committee will act as a planning committee to the P&T Committee. The MHA P&T will provide additional expertise in the area of mental health. Specifically, the MHA P&T Committee will: review research on mental health drugs; outline the needs and considerations of mental health consumers; and make specific recommendations on drugs to include on the preferred drug list to the P&T Committee.

### **Quality Improvement and Physician Education**

The MHA P&T Committee will bring best practices from quality improvement programs already in place, and will work with the P&T to develop new quality improvement programs to reduce inappropriate drug therapies as you have advised. Quality can be improved at the same

time costs are reduced by educating physicians in the areas of polypharmacy and prescribing patterns (e.g., reducing unnecessarily high-dosage levels and regimens).

We will also work with you to educate physicians regarding the cost of psychiatric drugs so that if a physician is equally inclined to prescribe several drugs in a class, he or she can select the least expensive medication.

### **Prior Authorization Approval Protocol**

Your input will be valuable as the P&T Committee develops prior authorization approval protocols. For example, it was suggested that individuals with high psychiatric inpatient readmission rates have prior authorization automatically granted.

We look forward to working with you to make the preferred drug list and prior authorization process a success for consumers and the Department. Enclosed for your review please find the proposed regulations. We would like to have comments back from you by September 6. Please contact me with other questions or comments at (410) 767-4664.

Sincerely,

Debbie I. Chang, M.P.H.  
Deputy Secretary  
Health Care Financing